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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/942,075 | 08/28/2001 | George Treacy | 0148.1135-010 | 6161 |

21005 7590 10/21/2005

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

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| EXAMINER |
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NOLAN, PATRICK J

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| ART UNIT | PAPER NUMBER |
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1644

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942,075

Applicant(s)

TREACY, GEORGE

Examiner

Patrick J. Nolan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Claims 1-12 are pending.
2. Claims 3-4, 7-8 and 11-12 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record set forth in the Paper mailed 2-25-05.

Applicant's has argued they will fulfill the deposit requirement upon a finding of allowable subject matter.

The rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

3. Claims 1-12 stands rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent 5,698,195 (AA), in view of Shah et al. (AY) and Lukacs et al. (AS), all of record, for reasons set forth in the paper mailed 2-25-05.

Applicant's arguments filed 7-27-05 have been fully considered but are not found persuasive.

The declaration under 37 CFR 1.132 filed 7-27-05 is insufficient to overcome the rejection of claims 1-12 based upon 35 USC 103 as set forth in the last Office action.

The declarant opinions were not found persuasive to remove the 35 USC 103 rejections because he argues the references independently. He provides very limited expert opinion on the primary reference the 5,698,195 patent. He only declares that the '195 patent discloses lung pathology generically, but does not disclose asthma. He provides no opinion as to why if one of skill in the art was to read the '195 patent and glean from it that any TNF-alpha mediated disease could be treated by administering the cA2 monoclonal antibody. The opinion that he declares in relation to the secondary reference is that Shah et al., do not provide evidence that would have taught one of ordinary skill in the art to effectively treat asthma or airway inflammation associated with an anti-TNF-alpha antibody. Shah et al., was relied upon to establish that TNF-alpha is an important mediator in asthma. The declarant does not refute this.

The declarant offers expert opinion in regards to Lukacs et al., but does not refute what Lukacs et al., is relied upon for, the teaching that TNF-alpha mediates the recruitment of neutrophils and eosinophils during airway inflammation.

The declarant also offers expert opinion on the reference Konno et al. Konno et al., is not part of the 35 USC 103 rejection.

Applicant's arguments filed 7-27-05 have been fully considered but are not found persuasive.

Applicant argues there was no expectation of success that using the cA2 monoclonal antibody taught by the '195 patent would treat asthma. The burden on the Examiner is to establish that one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success in treating asthma with the cA2 antibody. The '195 patent teaches treating any disease associated with abnormal levels of TNF-alpha. Shah et al., teaches people with asthma have abnormal levels of TNF-alpha. As recognized by applicant on page 2 of their response Shah et al., summarized the scientific rational in 1995 that supported TNF-alpha as an attractive target for asthma. Furthermore Applicant recognizes that "Shah expresses hope that an anti-TNF-alpha antibody would provide a new type of therapeutic intervention in the

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treatment of asthma". Applicant is also guided to the issued claims of US Patent 5,919,452, which recites the treatment of any TNF mediated disease by administering a TNF-alpha antibody. So there was ample expectation of success that administering TNF-alpha antibodies would treat any TNF-alpha mediated disease and that asthma is a TNF-alpha mediated disease.

Applicant has provided no evidence at the time of filing to dispute the scientific recognized fact that TNF-alpha was involved in the pathology of asthma.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


5. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

6. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

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If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.



Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

October 6, 2005